

interested persons may participate in open public hearings before FDA's advisory committees.

FDA has established an Advisory Committee Information Hotline (the hotline) using a voice-mail telephone system. The hotline provides the public with access to the most current information on FDA advisory committee meetings. The advisory committee hotline, which will disseminate current information and information updates, can be accessed by dialing 1-800-741-8138 or 301-443-0572. Each advisory committee is assigned a 5-digit number. This 5-digit number will appear in each individual notice of meeting. The hotline will enable the public to obtain information about a particular advisory committee by using the committee's 5-digit number. Information in the hotline is preliminary and may change before a meeting is actually held. The hotline will be updated when such changes are made.

MEETING: The following advisory committee meeting is announced:

Oncologic Drugs Advisory Committee

Date, time, and place. December 14, 1995, 8 a.m., Holiday Inn—Bethesda, Versailles Ballrooms I and II, 8120 Wisconsin Ave., Bethesda, MD.

Type of meeting and contact person. Open public hearing, 8 a.m. to 9 a.m., unless public participation does not last that long; open committee discussion, 9 a.m. to 5 p.m.; Stephen P. Pollitt or Adele S. Seifried, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4695, or FDA Advisory Committee Information Hotline, 1-800-741-8138 (301-443-0572 in the Washington, DC area), Oncologic Drugs Advisory Committee, code 12542.

General function of the committee. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the treatment of cancer.

Agenda—Open public hearing. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Those desiring to make formal presentations should notify the contact person before December 8, 1995, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time required to make their comments.

Open committee discussion. The committee will discuss: (1) FDA

oncology initiatives, (2) new drug application (NDA) 20-587, Sterile Aerosol Talc (Talc of Luzenac PR 784, Bryan Corp.), for treatment of malignant pleural effusion, and (3) product license application (PLA) 94-0308, NR-LU-10 Fab (Karl Thomae GmbH), for primary staging of patients with biopsy confirmed small cell lung cancer.

FDA public advisory committee meetings may have as many as four separable portions: (1) An open public hearing, (2) an open committee discussion, (3) a closed presentation of data, and (4) a closed committee deliberation. Every advisory committee meeting shall have an open public hearing portion. Whether or not it also includes any of the other three portions will depend upon the specific meeting involved. There are no closed portions for the meetings announced in this notice. The dates and times reserved for the open portions of each committee meeting are listed above.

The open public hearing portion of each meeting shall be at least 1 hour long unless public participation does not last that long. It is emphasized, however, that the 1 hour time limit for an open public hearing represents a minimum rather than a maximum time for public participation, and an open public hearing may last for whatever longer period the committee chairperson determines will facilitate the committee's work.

Public hearings are subject to FDA's guideline (subpart C of 21 CFR part 10) concerning the policy and procedures for electronic media coverage of FDA's public administrative proceedings, including hearings before public advisory committees under 21 CFR part 14. Under 21 CFR 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants.

Meetings of advisory committees shall be conducted, insofar as is practical, in accordance with the agenda published in this Federal Register notice. Changes in the agenda will be announced at the beginning of the open portion of a meeting.

Any interested person who wishes to be assured of the right to make an oral presentation at the open public hearing portion of a meeting shall inform the contact person listed above, either orally or in writing, prior to the meeting. Any person attending the hearing who does not in advance of the meeting request an opportunity to speak will be allowed to make an oral presentation at the

hearing's conclusion, if time permits, at the chairperson's discretion.

The agenda, the questions to be addressed by the committee, and a current list of committee members will be available at the meeting location on the day of the meeting.

Transcripts of the open portion of the meeting may be requested in writing from the Freedom of Information Office (HFI-35), Food and Drug Administration, rm. 12A-16, 5600 Fishers Lane, Rockville, MD 20857, approximately 15 working days after the meeting, at a cost of 10 cents per page. The transcript may be viewed at the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, approximately 15 working days after the meeting, between the hours of 9 a.m. and 4 p.m., Monday through Friday. Summary minutes of the open portion of the meeting may be requested in writing from the Freedom of Information Office (address above) beginning approximately 90 days after the meeting.

This notice is issued under section 10(a)(1) and (2) of the Federal Advisory Committee Act (5 U.S.C. app. 2), and FDA's regulations (21 CFR part 14) on advisory committees.

Dated: November 20, 1995.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 95-29085 Filed 11-28-95; 8:45 am]

BILLING CODE 4160-01-F

Grassroots Regulatory Partnership Meeting; Southwest Region; Human and Veterinary Drug Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of External Affairs, Office of Regulatory Affairs, Office of the Southwest Region, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, and Center for Veterinary Medicine) is announcing a free public meeting as a followup to a meeting held in April 1995. FDA Office of the Southwest Region will meet with interested persons in the Southwest Region to address specific issues related to the human and veterinary drug industry. The agency is holding this meeting to promote the President's initiative for a partnership approach between front-line regulators and the people affected by the work of this agency.

DATES: The public meeting will be held on Thursday, December 7, 1995, from 8:30 a.m. to 3:30 p.m.

ADDRESSES: The public meeting will be held at the Sheraton Denver West Hotel, 360 Union Blvd., Lakewood, CO.

FOR FURTHER INFORMATION CONTACT: Virlie M. Walker, FDA Denver District, Bldg. 20, Entrance W-10, Denver Federal Center, Sixth and Kipling Sts., Denver, CO 80225-0087, 303-236-3018, FAX 303-236-3551.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnership Meetings would be held. This document announces a followup meeting to the one held on April 24, 1995, in Dallas, TX. Those persons interested in attending this public meeting should FAX their registration including name(s), affiliation, address, telephone and FAX numbers, and any specific questions about the workshop to Virlie M. Walker (address above), 303-236-3551. There is no registration fee for this meeting. However due to space limitations, early registration is required. The goal of this meeting is to listen to concerns and ideas, and to identify next steps for the agency.

Dated: November 22, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-29130 Filed 11-28-95; 8:45 am]

BILLING CODE 4160-01-F

Grassroots Regulatory Partnership Meeting; Atlanta and Florida District Offices; Medical Device Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of a public meeting.

SUMMARY: The Food and Drug Administration (FDA) (Office of Regulatory Affairs, Southeast Region/Atlanta and Florida District Offices) is announcing a free public meeting as a followup to a meeting held in April 1995. FDA Atlanta and Florida District Offices will meet with interested persons in Georgia, Florida, North Carolina, and South Carolina to address specific issues related to the medical device industry, Atlanta and Florida Districts, and FDA. The agency is holding this meeting to promote the President's initiative for a partnership approach with front-line regulators and the people affected by the work of this agency, and to create local partnerships.

DATES: The public meeting will be held on Thursday, December 7, 1995, from 8 a.m. to 3:30 p.m.

ADDRESSES: The public meeting will be held at the Sheraton Colony Square Hotel, Peachtree at 14th St., Atlanta, GA.

FOR FURTHER INFORMATION CONTACT:

Sheila Bayne-Lisby, FDA Atlanta District, 60 Eighth St. NE., Atlanta, GA 30309, 404-347-7355, or FAX 404-347-1912, or

Lynne Isaacs, FDA Florida District, 7200 Lake Ellenor Dr., suite 120, Orlando, FL 32809, 407-648-6922 ext. 202, or FAX 407-648-6881.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 20, 1995 (60 FR 19753), FDA announced that a series of Grassroots Regulatory Partnership meetings would be held. This document announces a followup to the one held on April 25, 1995, in Atlanta, GA. Those persons interested in attending this meeting should FAX their comments and registration including name, firm/organization name, address, and telephone number to 404-347-1912. There is no registration fee for this meeting. However, due to space limitations advance registration is required, and all interested parties are encouraged to register early. The goal of this meeting is to "listen" to concerns and ideas, and to identify next-steps for the agency.

Dated: November 22, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 95-29131 Filed 11-28-95; 8:45 am]

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Health Care Financing Administration

Public Information Collection Requirements Submitted for Public Comment and Recommendations

AGENCY: Health Care Financing Administration, Department of Health and Human Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summaries of proposed collections for public comment. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to

be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection

Request: Revision of a currently approved collection; **Title of Information Collection:** Medicare Uniform Institutional Provider Bill; **Form No.:** HCFA-1450; **Use:** Medicare reimbursement of claims. This form is the standardized form used in the Medicare/Medicaid program to apply for reimbursement for covered services by all providers that accept Medicare/Medicaid assigned claims. It will reduce cost and administrative burdens associated with claims since only one coding system is used and maintained. **Frequency:** On occasion; **Affected Public:** Business or other for-profit, not-for-profit institutions, Federal Government, and State, local or tribal government; **Number of Respondents:** 123,432,041; **Total Annual Hours Requested:** 1,890,490.

2. Type of Information Collection

Request: Extension of a currently approved collection; **Title of Information Collection:** End Stage Renal Disease Medical Evidence Report Medicare Entitlement and/or Patient Registration; **Form No.:** HCFA-2728; **Use:** This form captures the necessary medical information required to determine Medicare eligibility of an end stage renal disease claimant. It also captures the specific medical data required for research and policy decisions on this population as required by law. **Frequency:** Annually; **Affected Public:** Individuals or households, business or other for-profit, not-for-profit institutions; **Number of Respondents:** 60,000; **Total Annual Hours Requested:** 25,200.

To request copies of the proposed paperwork collections referenced above, call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections should be sent within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Financial and Human Resources, Management Planning and Analysis Staff, Attention: Louis Blank, Room C2-26-17, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.